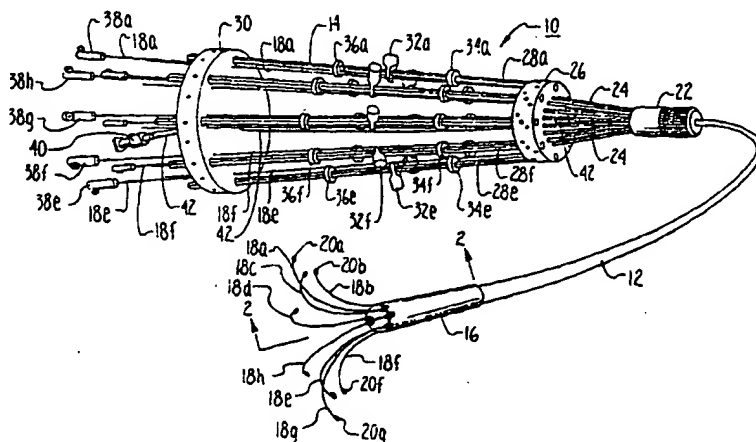


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁵ : A61B 5/042	A1	(11) International Publication Number: WO 95/05773 (43) International Publication Date: 2 March 1995 (02.03.95)
<p>(21) International Application Number: PCT/US93/07881</p> <p>(22) International Filing Date: 23 August 1993 (23.08.93)</p> <p>(71) Applicant: CARDIAC PATHWAYS CORPORATION [US/US]; 995 Benecia Avenue, Sunnyvale, CA 94086 (US).</p> <p>(72) Inventors: WALDMAN, Lewis, K.; 334 Kolmar Street, La Jolla, CA 92037 (US). CHEN, Peng, Sheng; 474 Paulette Place, La Canada, CA 91011 (US).</p> <p>(74) Agent: BACHAND, Edward, N.; Flehr, Hobbach, Test, Albritton & Herbert, Suite 3400, 4 Embarcadero Center, San Francisco, CA 94111-4187 (US).</p>	<p>(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p>Published <i>With international search report.</i></p>	

(54) Title: **ENDOCARDIAL ELECTRICAL MAPPING CATHETER**

(57) Abstract

An endocardial mapping catheter (10) includes an actuator assembly (14) and an elongated hollow support sheath (12) which extends from the actuator assembly (14). A plurality of electrical probes (18 a-h) are slidingly disposed for independent movement through the sheath (12), and each probe (18) is attached to the actuator assembly (14) for individual manipulation. A guide (16) is mounted on the end of the sheath (12) opposite the actuator assembly (14), to radially deploy each electrical probe (18) along a separate favorable trajectory as the probe is manipulated. In operation, the probes (18) are initially retracted into the sheath (12). Once the guide (16) is positioned as desired, all of the probes (18) are individually deployed until they have each made contact with the endocardium of the left ventricle. Timed responses are obtained from the probes (18), and a series of such responses from various guide locations in the left ventricle are recorded to accomplish circumferential endocardial mapping of the heart.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

ENDOCARDIAL ELECTRICAL MAPPING CATHETER

FIELD OF THE INVENTION

The present invention pertains generally to diagnostic catheters. More particularly, the present invention pertains to a catheter which individually and selectively
5 positions a plurality of electrodes at separate locations on the endocardium of the left ventricle of a heart to simultaneously record the electrical responses from these locations during contraction of the heart muscle. The present invention is particularly, but not exclusively,
10 useful for the circumferential endocardial mapping of the left ventricle to locate the ectopic focus of an abnormally functioning heart muscle.

BACKGROUND OF THE INVENTION

As is well known, the heart muscle effectively acts as
15 a pump which maintains the circulation of blood through the body. More particularly, the left ventricle is that portion of the heart which propels blood in systemic circulation through the body to supply the body tissues with nutrients. In lay terms, this pumping action results
20 from contractions of the heart muscle which are more commonly referred to as the heart beat.

Normally, contractions of the heart muscle (i.e. heart beats) result from an excitation wave of electrical impulses which originate at the atrium, which propagate via
25 the atrioventricular node to the ventricles, and which progress outwardly through conductive tissue in the endocardium. This is normal, and the rhythmic repetition of the heart beat is an indicator of good health. It happens, however, that for a diseased heart there are
30 sometimes variations from the normal rhythm of the heart beat which are manifested as abnormal spontaneous contractions. These abnormalities are clinically referred to as arrhythmia, and they can cause numerous unwanted complications for a patient. Thus, for many reasons, it is
35 desirable to locate the site of arrhythmogenesis or ectopic

focus of an arrhythmia with the hope that medical intervention can cure the problem.

As is well known, the ectopic focus of an arrhythmia is usually located in the endocardium. This mislocation of the initiation of contraction from the atrium to what is now the ectopic focus is what causes the arrhythmia. Since heart contractions result from the progression of an excitation wave of electrical impulses, location of the ectopic focus is merely a matter of identifying the point from where the abnormal excitation wave originates. Several catheter electrodes have been proposed for this purpose. The following specifically cited references are representative of these catheters.

U.S. Patent No. 4,628,937 to Hess et al. for an invention entitled "Mapping Electrode Assembly" is an example of a device which is used for the epicardial or endocardial mapping of the electrical impulses from the heart. According to the teachings of the Hess et al. device, the electrodes are symmetrically arrayed within a mounting cup that conforms to the organ being mapped. Consequently the electrodes of the Hess et al. device are set relative to each other and the efficacy of their displacement is dependent on the ability of the cup to conform to the particular surface.

U.S. Patent No. 4,699,147 to Chilson et al. for an invention entitled "Intraventricular Multielectrode Cardial Mapping Probe and Method for using Same" discloses a device which positions the electrodes along wire assemblies which can be extended from a catheter to create an elliptical envelope. This envelope is then incrementally rotatable within the heart chamber while electrical potentials are measured and recorded at different points on the endocardium. For this device, all of the electrodes are symmetrically deployed as a unit. Thus, there is no individual control over the placement of any given electrode. Further, there is no assurance that all of the

electrodes have, in fact, made contact with the surface of the endocardium.

U.S. Patent No. 4,522,212 to Gelinas et al. for an invention entitled "Endocardial Electrode" discloses a plurality of spring legs having insulated conductors which are connected to respective sets of spaced electrodes. In operation these spring legs of the Gelinas et al. device are allowed to extend apart to cause the electrodes to engage the wall tissue. Again, as with the other above cited references, there is no individual control over each of the separate electrodes. Consequently, there is no assurance that each electrode is properly placed, or that there is even contact between the electrode and the endocardium.

None of the above examples either individually or collectively disclose the structure or the cooperation of structure which is used to accomplish the objects of the present invention.

In light of the above it is an object of the present invention to provide an endocardial mapping catheter which has a plurality of electrode probes which can each be independently manipulated to achieve non-axisymmetric placement of the electrodes against the endocardium of the left ventricle. Another object of the present invention is to provide an endocardial mapping catheter which establishes a favorable trajectory for each electrode during the placement process that directs the electrode into contact with the endocardium from a direction that is substantially perpendicular to the endocardium. Still another object of the present invention is to provide an endocardial mapping catheter which positions the plurality of electrodes circumferentially against the endocardium in a substantially coplanar arrangement. Yet another object of the present invention is to provide an endocardial mapping catheter which can be positioned, and repositioned, within the left ventricle of a heart to make successive

recordings of electrical impulses from the endocardium for use in preparing an isochronal map of these impulses. Another object of the present invention is to provide an endocardial mapping catheter which is easy to use, relatively simple to manufacture, and comparatively cost effective.

SUMMARY OF THE INVENTION

A catheter, for circumferentially mapping electrical responses from the left ventricle of the heart of a patient, includes a plurality of individually manipulable electrode probes which are structurally combined with an actuator assembly, a flexible support sheath and a probe guide. For the catheter of the present invention, the support sheath is a hollow elongated tube and the plurality of electrode probes are slidably disposed inside the sheath. The actuator assembly is attached to the proximal end of the support sheath, and a plurality of actuation levers are slidably mounted on the actuator assembly. In addition to being slidably mounted on the actuator assembly, each of these levers is fixedly attached to the proximal end of one of the electrode probes. The probe guide, which is formed with a plurality of flared passageways is mounted on the distal end of the support sheath, and the distal end of each electrode probe is positioned to slide through one of the passageways of the guide.

In the operation of the endocardial mapping catheter of the present invention, the guide at the distal tip of the catheter is inserted into the left ventricle and positioned therein as desired. The operator then individually manipulates each actuation lever to move a respective electrode probe through the sheath in a distal direction. This action sequentially deploys all of the electrode probes through the guide of the catheter and into the left ventricle. In each case, the deployment of an

electrode probe from the probe guide is accomplished along a favorable trajectory from the guide until the distal tip of the electrode probe contacts the endocardium. In accordance with the present invention, this favorable trajectory extends from the probe guide and into a line which is substantially perpendicular to the surface of the endocardium. All of the electrode probes are thus sequentially deployed radially from the guide to circumferentially position their respective distal tips against the endocardium in a substantially coplanar arrangement.

Once the distal tips of all electrode probes have been deployed into contact with the endocardium, the electrical responses resulting from heart muscle activity are recorded by electronic recording equipment associated with the catheter. After sufficient data have been obtained with the catheter in a particular position, the electrode probes can be withdrawn and the guide at the distal tip of the catheter can be repositioned as desired. Additional data can thus be obtained from several locations of the catheter in the left ventricle and an isochronal map can be developed from the recorded data. With this map, the site of arrhythmogenesis or ectopic focus on the heart can be located.

The novel features of this invention, as well as the invention itself, both as to its structure and its operation will be best understood from the accompanying drawings, taken in conjunction with the accompanying description, in which similar reference characters refer to similar parts, and in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1A is a perspective view of the endocardial electrical mapping catheter of the present invention;

Figure 1B is a perspective view of the probe guide portion of the catheter when the probes of the catheter are retracted;

Figure 2A is an exploded cross-sectional view of the guide of the catheter of the present invention as seen
5 along the line 2-2 in Figure 1A;

Figure 2B is a cross-sectional view of the guide shown in Figure 2A when assembled and with probes extending therethrough;

Figure 3 is a perspective view of the heart of a patient with the catheter of the present invention inserted into the left ventricle, portions of the heart wall are removed for clarity and the guide is shown in phantom to indicate variations in the positioning of the guide inside
10 the left ventricle of the heart;

Figure 4 is a cross-sectional view of the heart with inserted catheter as seen along the line 4-4 in Figure 3;

Figure 5 is a representative graph of timed responses from each of the probes of the catheter of the present invention during sequential cardiac cycles; and
20

Figure 6 is a representation of three locations from the apex to the base of the left ventricle at which responses were recorded during a procedure using the catheter of the present invention.

25

DESCRIPTION OF PREFERRED EMBODIMENTS

Referring initially to Figure 1A, an endocardial mapping catheter in accordance with the present invention is shown and is generally designated 10. As shown, the catheter 10 includes a hollow elongated support sheath 12
30 which is formed with a lumen, and which is sufficiently flexible to be inserted through selected arteries of a body. An actuator assembly 14 is attached to the proximal end of the sheath 12, and a probe guide 16 is attached to its distal end. As indicated in Figure 1A, a plurality of
35 individual electrode probes 18 a-h, are disposed inside the

hollow sheath 12 and extend therethrough from the actuator assembly 14 to the probe guide 16. It is to be appreciated that there may be any number of electrode probes 18 desired by the operator, and there is no reason for limiting the catheter 10 to the use of only eight such electrode probes 18 a-h as shown in the Figures. For brevity, individual probes may be referred to hereinafter as a probe 18.

Figure 1A also shows that each electrode probe 18 has a tip 20 at its distal end. Preferably, the tip 20 is a bipolar electrode because electrical responses can be more clearly identified using a bipolar electrical structure. A unipolar tip 20, however, is within the contemplation of the present invention. Regardless what electrical structure is used for the electrode probes 18 a-h, it will be appreciated by cross referencing Figure 1A with Figure 1B that the catheter 10 is used to deploy the tips 20 of electrode probes 18 a-h from the probe guide 16. Specifically, it is the intention of the present invention that the electrode probes a-h be individually manipulable between a retracted configuration (shown in Figure 1B) and a collectively deployed configuration (shown in Figure 1A). The mechanics of how this is accomplished will be best appreciated by considering the actuator assembly 14 as it is shown in Figure 1A.

First, Figure 1A shows that a connector assembly 22 is used to join the actuator assembly 14 to the sheath 12. Next, a plurality of rigid spacer bars 24 are shown attached between the connector assembly 22 and a support disc 26. In turn, a plurality of rigid guide rods 28 a-h connect and position a base plate 30 relative to the support disc 26. It will be noticed in Figure 1A that the guide rods 28 a-h are flared outwardly in the proximal direction from the support disc 26 toward the base plate 30. This is done to facilitate the manipulability of catheter 10. In any event, the connector assembly 22, support disc 26 and base plate 30, together with their

respective interconnecting spacer bars 24 and guide rods 28 a-h, establish a rigid platform structure from which the individual electrode probes 18 of the catheter 10 can be manipulated.

5 Still referring to Figure 1A, it will be seen that a plurality of actuation levers 32 a-h are slidably mounted on respective individual guide rods 28 a-h for movement between distal stops 34 a-h and proximal stops 36 a-h. Importantly, each guide rod 28 should have a cross section
10 profile, such as a square or rectangle, which will prevent any rotation of the associated actuation lever 32 a-h about the longitudinal axis of the guide rod 28 a-h. As will also be appreciated by reference to Figure 1A each of the actuation levers 32 a-h is fixedly attached to a respective
15 electrode probe 18 a-h. Thus, any manipulation of the actuation levers 32 a-h between the distal stops 34 and the proximal stops 36 will result in a corresponding distal or proximal movement of the electrode probes 18 a-h. Figure 1A also shows that an electrical connector 38 a-h is
20 attached to the distal end of a respective electrode probe 18 a-h.

The catheter 10 also includes a nozzle 40 that is connected to a hose 42 which extends through the actuator assembly 14 and which is connected in fluid communication
25 with the lumen of hollow support sheath 12. This nozzle 40 is attachable to a source of fluid (not shown), such as a saline solution, which can be used to flush the catheter 10 through the sheath 12 and probe guide 16 to help maintain its operability.

30 While the actuator assembly 14, as disclosed above, is important and necessary for manipulating the individual deployment of the electrode probes 18 a-h from the catheter 10, the trajectory which is followed by each electrode probe 18 a-h when it is deployed is, at least, of equal
35 importance. The structure of catheter 10 which establishes the favorable trajectory of each electrode probe 18 is the

probe guide 16. An understanding of the probe guide 16 will be best appreciated with reference to Figures 2A and 2B.

Referring first to the exploded view of guide probe 16 in Figure 2A, it will be seen that guide probe 16 includes a base 44, and a head 46 which is held on the base 44 by a screw 48. More specifically, the base 44 is formed with a plurality of channels 50 a-h. Also, the base 44 has a bracket 52 which is formed with a plurality of holes 54 a-h that communicate respectively with the channels 50 a-h. As shown, each of the channels 50 a-h has a curved end 56 a-h, and the bracket 52 is formed with a threaded orifice 58. In an alternate embodiment, the base 44 can be made without the channels 50 a-h. On the other hand, the head 46 has a plurality of grooves 60 a-h which are formed to mate with the respective channels 50 a-h of the base 44 to create passageways 62 a-h (shown in Figure 2B). To create these passageways 62 a-h, the screw 48 is inserted through the bore 64 of head 46 and threadably engaged with the threaded orifice 58 of base 44. This combination of components is, perhaps, best appreciated by reference to Figure 2A. The sheath 12 can be joined to the detent 66 of base 44 by any means well known in the pertinent art, such as by solvent bonding.

25

OPERATION

In the operation of the endocardial mapping catheter 10 of the present invention, the catheter 10 is inserted into the left ventricle 68 of the heart 70 of a patient substantially as shown in Figure 3. Additionally, Figure 3 also shows the catheter 10 in its electrical connection with an electronic device 72. As will become more apparent, the electronic device 72 can be of any type well known in the pertinent art which is able to record the electrical signals from the heart 70 which are picked up by the various electrode probes 18 a-h.

Figure 3 further indicates that the probe guide 16 at the distal end of catheter 10 can be moved and repositioned within the left ventricle 68. Specifically, Figure 3 shows three different deployment patterns for the catheter 10 which are successively designated 74, 74' and 74". Importantly, for each deployment pattern 74, 74' or 74", the individual electrode probes 18 a-h are separately and individually extendable from the probe guide 16 along what is termed here, a favorable trajectory. Essentially, this is taken to mean that the tip 20 of any particular electrode probe 18 is deployed from the probe guide 16 along a path which approaches and contacts the endocardium 76 of the left ventricle 68 from a direction that is substantially perpendicular to the surface of the endocardium 76. The benefits to be obtained from this cooperation of structure are two-fold. First, it allows the electrode probe 18 to contact the endocardium from a direction which has the optimal probability of establishing a good electrical contact between the electrode probe 18 and the endocardium 76. Second, it allows the individual electrode probe 18 to continue to be deployed from the catheter 10 until there is such contact. A specific example will be instructive.

Consider the catheter 10 to be in the deployment pattern 74' as shown in Figure 3. Further, consider that Figure 4 corresponds to the positioning of the electrode probes 18 in deployment pattern 74'. Initially, when considering the electrode probes 18 a-h collectively, it can be appreciated that the deployed tips 20 a-h of the plurality of electrode probes 18 a-h are substantially coplanar when in contact with the endocardium 76. Next, when considering a specific electrode probe 18 (e.g. electrode probe 18d) it can be appreciated that the tip 20d of the electrode probe 18d contacts the endocardium 76 from a direction that is substantially perpendicular to the surface of the endocardium. Indeed, this is so for all

electrode probes 18 a-h regardless of the topography of the endocardium 76 at the particular location where the tip 20 a-h makes its contact.

Another important structural capability of the catheter 10 is that the location of probe guide 16 in left ventricle 68 need not be established with precision for any particular deployment pattern 74, 74' or 74". As shown in Figure 4, the probe guide 16 is not centered in the left ventricle 68. Still, the various electrode probes 18 a-h are each capable of being deployed from the catheter 10 and into contact with the endocardium 76. For example, the electrode probe 18e is not deployed from probe guide 16 as far as is the electrode probe 18h. Nevertheless, both probes 18e and 18h are in contact with the endocardium 76.

From the above it will be appreciated that an operator can initially manipulate all of the actuation levers 32 a-h by drawing them proximally toward the proximal stops 36 a-h to withdraw the tips 20 of electrode probes 18 a-h into the retracted configuration for probe guide 16 shown in Figure 1B. The probe guide 16 at the distal end of support sheath 12 can then be inserted into the left ventricle 68 using any approved medical procedure. Once the probe guide 16 is properly positioned inside the left ventricle 68 of heart 70 using well known techniques, such as by fluoroscopy, the electrode probes 18 a-h can be individually deployed along favorable trajectories into a deployment pattern 74. Electronic responses from the heart 70 can then be recorded by the electronic device 72. After a sufficient number of electronic responses has been recorded with catheter 10 in the deployment pattern 74, the electrode probes 18 a-h can be withdrawn into their retracted configuration. The probe guide 16 can then be repositioned within the left ventricle 68 for reconfiguration into the deployment pattern 74' and, subsequently from deployment pattern 74', into the deployment pattern 74". In each case, the operator is able to individually manipulate an actuation lever 32 on the

actuator assembly 14 to either retract or deploy the corresponding electrode probe 18. Furthermore, during each deployment, the particular electrode probe 18 is deployed along a favorable trajectory.

5 Figure 5 shows a representative time sequence of electrical responses resulting from contractions of the heart 70 as they would be received by the catheter 10 from the heart 70 during any particular deployment pattern 74. For a more specific example, consider that the catheter 10
10 is in the deployment pattern 74 shown in Figures 3 and 4. For the example of this deployment pattern 74, Figure 5 shows that the recorded electrical responses 78 a-h, as obtained through the respective electrode probe 18 a-h, occur at different times. It happens that, because an
15 arrhythmia occurs as waves, the earliest recorded response is nearer the ectopic focus. Thus, Figure 5 indicates that for the particular contraction of heart 70 which caused the electrical responses 78 a-h, the electrode probes 18a and 18h were closest to the ectopic focus, and that the
20 electrode probe 18d was farthest from the ectopic focus. Not surprisingly, the subsequent set of recorded electrical responses 80 a-h which are obtained by catheter 10 in this same deployment pattern 74 is substantially similar. Several such responses can be obtained, as desired by the
25 operator. Among these responses recorded (78, 80), one will be chosen for analysis. The timing of the chosen activations relative to a selected reference time point, such as the onset of the QRS complex on the surface electrogram, will be assigned to one of the electrode
30 locations shown in Figure 6 marked 78a/80a to 78h/80h.

 In Figure 6 the electrical responses 78/80 a-h et seq. are plotted around the circumference designated to correspond with deployment pattern 74. Other circumferences are obtained corresponding to the deployment
35 patterns 74' and 74'', and the earliest responses are identified to locate the ectopic focus. In the

contemplation of the present invention, as many deployment patterns may be accomplished as is deemed necessary by the operator to properly locate the site of arrhythmogenesis.

While the particular endocardial mapping catheter as
5 herein shown and disclosed in detail is fully capable of
obtaining the objects and providing the advantages herein
before stated, it is to be understood that it is merely
illustrative of the presently preferred embodiments of the
invention and that no limitations are intended to the
10 details of the construction or design herein shown other
than as defined in the appended claims.

We claim:

1. An endocardial mapping catheter which comprises:
an elongated flexible support sheath having a
proximal end and a distal end, said sheath having a
5 lumen extending lengthwise therethrough;
a plurality of electrical probes, each of said
probes having a proximal end and a distal end and
being slidably disposed in said lumen;
a guide attached to said distal end of said
10 support sheath, said guide having a plurality of
passageways separately receiving one said probe to
radially deploy said distal end of each said probe
along a favorable trajectory from said guide as each
said probe is individually moved distally through said
15 lumen and said passageway;
a plurality of guide rods, each said guide rod
having a distal end and a proximal end; and
a plurality of actuation levers, each said
actuation lever being slidably mounted on one of said
20 guide rods and fixedly attached to one of said probes
for moving said probe to deploy said distal end of
said probe.
2. A catheter as recited in claim 1 for measuring
electrical responses from the endocardium of the left
25 ventricle of the heart of a patient to ascertain the origin
of an arrhythmia, wherein each said rod has a substantially
rectangular cross-section and each said actuation lever is
engageable with a respective said rod and is manipulable to
individually and selectively deploy each said electrical
30 probe into contact with the endocardium of the left
ventricle to simultaneously measure said electrical
responses from each said probe on substantially coplanar
portions of the endocardium.

3. A catheter as recited in claim 2 further comprising means for recording said electrical responses.

4. A catheter as recited in claim 3 further comprising means for outwardly flaring said guide rods in
5 a proximal direction to facilitate manipulation of said actuation levers.

5. A catheter as recited in claim 4 wherein said flaring means comprises a base attached to said distal ends of said plurality of guide rods, and a flaring disc
10 distanced from said base and attached to said proximal ends of said plurality of guide rods.

6. A catheter as recited in claim 5 further comprising means for injecting fluid through said lumen of said support sheath and through said plurality of
15 passageways in said guide.

7. A catheter as recited in claim 6 further comprising a plurality of electrical connectors, each said electrical connector being attached to one of said proximal ends of said probes for establishing an electrical
20 connection between said probe and said means for recording said electrical responses.

8. A catheter as recited in claim 7 wherein at least one of said probes is a bi-polar wire.

9. An endocardial mapping catheter for determining
25 electrical responses from portions of the endocardium of the left ventricle of the heart of a patient to ascertain the origin of an arrhythmia which comprises:

a plurality of electrode probes wherein each of said probes has a proximal end and a distal end;

means for collectively inserting said probes into said left ventricle;

5 means for individually and selectively deploying each said electrode probe into contact with said endocardium to circumferentially measure said electrical responses from each said probe on substantially coplanar portions of said endocardium;

a plurality of guide rods, each said guide rod having a distal end and a proximal end; and

10 a plurality of actuation levers, each said actuation lever being slidably mounted on one of said guide rods and fixedly attached to one of said probes for moving said probe to deploy said distal end of said probe.

15 10. A catheter as recited in claim 9 wherein said means for collectively inserting said probes into said left ventricle is an elongated flexible support sheath having a proximal end and a distal end, said sheath having a lumen extending lengthwise therethrough, and wherein each of said
20 probes is slidably disposed in said lumen.

11. A catheter as recited in claim 10 wherein said means for deploying each said probe comprises a guide attached to said distal end of said support sheath, said guide having a plurality of passageways separately
25 receiving one said probe and radially deploying said distal end of each said probe along a favorable trajectory as each said probe is individually moved distally in said lumen and through said passageway.

12. A catheter as recited in claim 11 further
30 comprising means for outwardly flaring said guide rods in a proximal direction to facilitate manipulation of said actuation levers, said flaring means including a base attached to said distal ends of said plurality of guide

rods, and a flaring disc distanced from said base and attached to said proximal ends of said plurality of guide rods.

13. A catheter as recited in claim 12 wherein said
5 guide rods have substantially rectangular cross sections to inhibit rotation of said actuation levers and said probes, and said catheter further comprises means for injecting fluid through said lumen of said support sheath and through said plurality of passageways in said guide.

10 14. A catheter as recited in claim 13 further comprising a means for recording said electrical responses and a plurality of electrical connectors, each said electrical connector being attached to one of said proximal
15 ends of said probes for establishing an electrical connection between said probe and said means for recording said electrical responses.

15. A catheter as recited in claim 14 wherein at least one of said probes is a bi-polar wire.

16. A method for measuring electrical responses from
20 portions of the endocardium of the left ventricle of the heart of a patient to ascertain the origin of an arrhythmia using an endocardial mapping catheter comprising a hollow elongated flexible support sheath having a proximal end and a distal end, a plurality of electrical probes slidably
25 disposed in the sheath, each said probe having a distal end, a guide attached to the distal end of the support sheath to radially deploy the distal ends of the probes along a favorable trajectory as each probe is individually moved distally through the support sheath, the catheter
30 further comprising an actuator assembly having a plurality of guide rods and a plurality of actuation levers with each lever slidably mounted on one of the guide rods and fixedly

attached to one of the probes for moving the probe to deploy the distal end of the probe; the method comprising the steps of:

- 5 A) Selectively positioning said guide of said support sheath in said left ventricle;
- B) Individually deploying said probes to establish electrical contact between said probes and said endocardium of said left ventricle;
- 10 C) Recording electrical responses from said endocardium through said probes for a selected number of cardiac cycles;
- D) Withdrawing said probes into said sheath;
- E) Repositioning said guide in said left ventricle to repeat steps B, C, and D, as necessary;
- 15 and
- F) Mapping the recorded electrical responses from said endocardium to locate the site of arrhythmogenesis.

17. A method as recited in claim 16 wherein said
20 deploying step is accomplished by sequentially extending substantially diametrically opposite probes, in pairs, until all said probes are placed in contact with the endocardium for circumferential endocardial mapping.

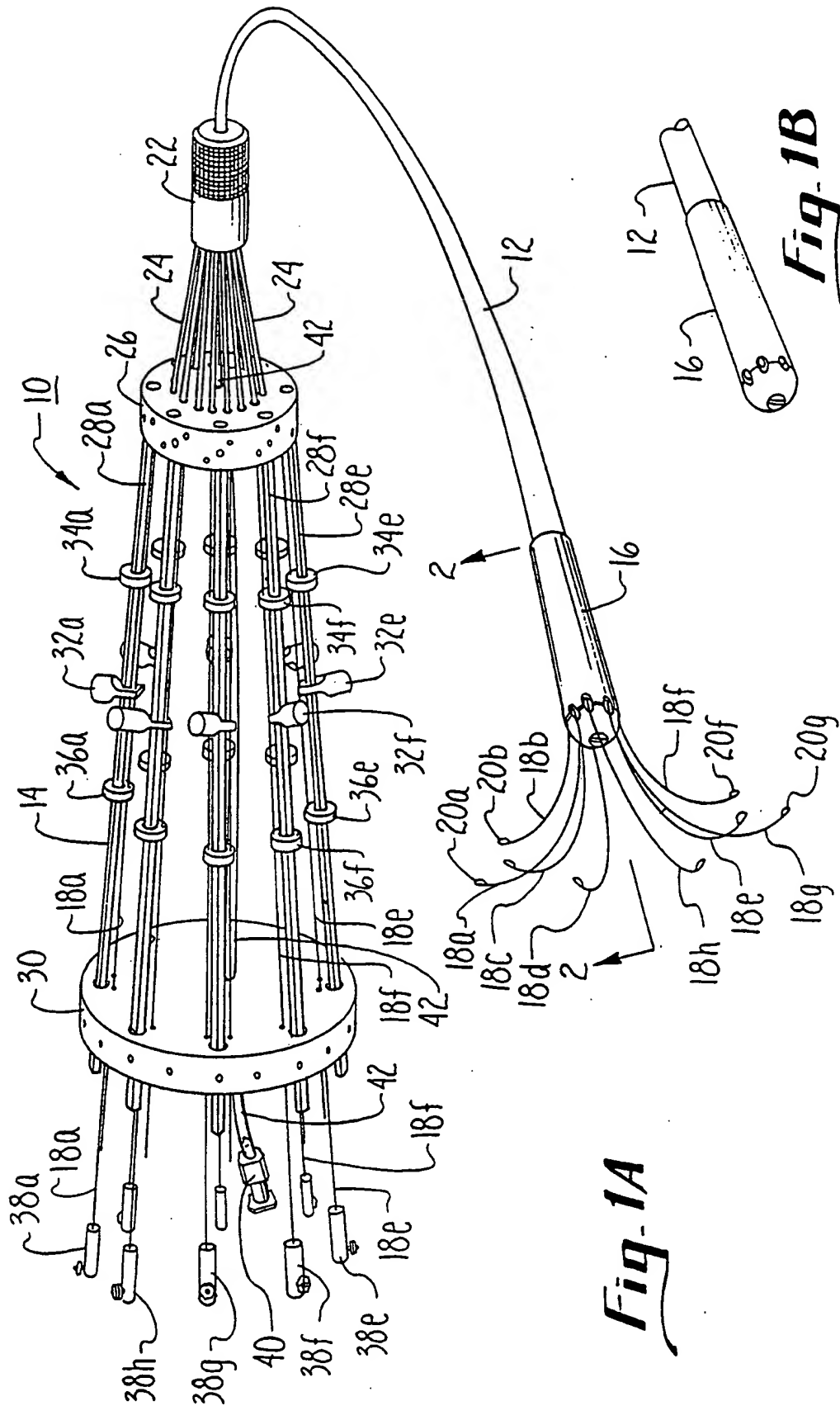
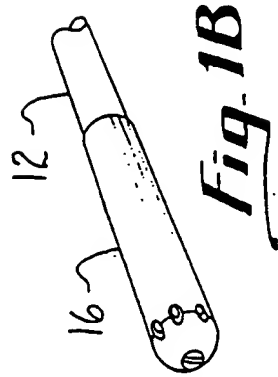


Fig. 1A



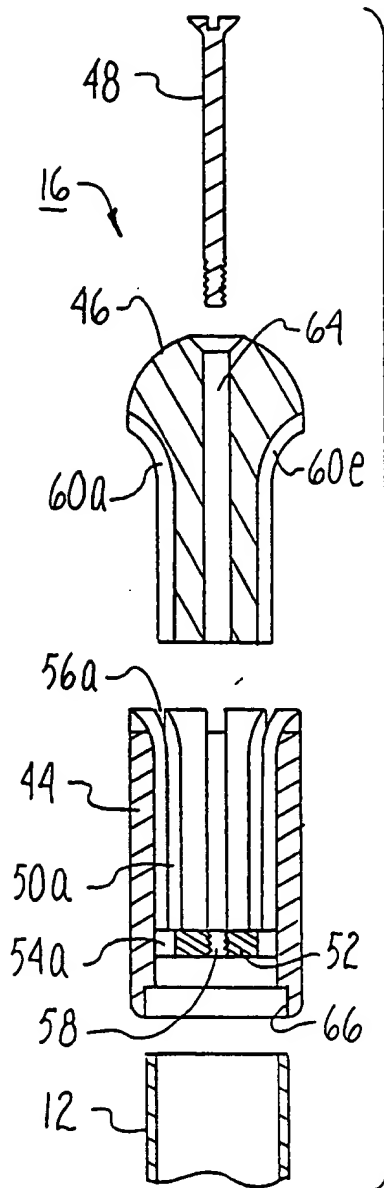


Fig. 2A

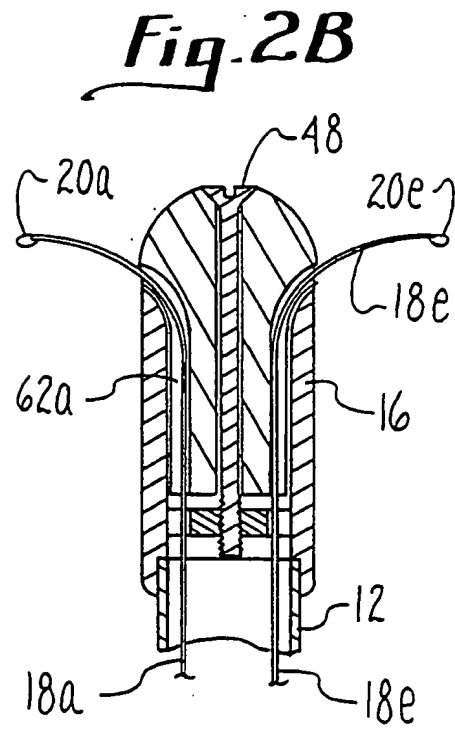


Fig. 2B

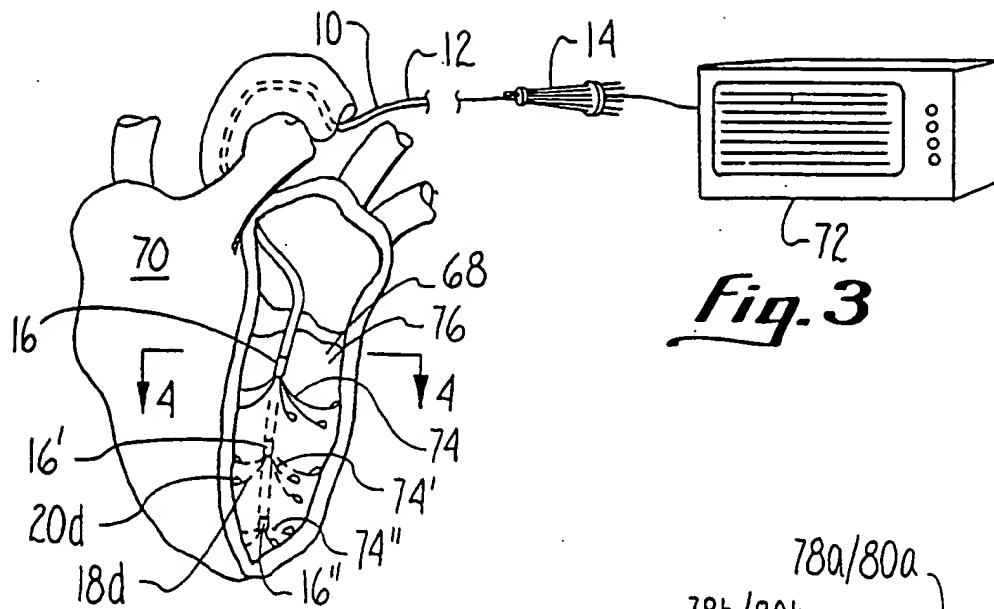


Fig. 3

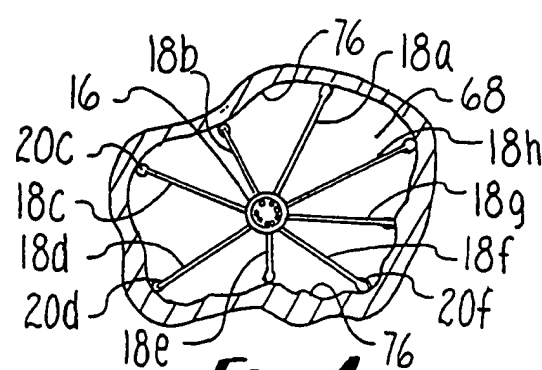


Fig. 4

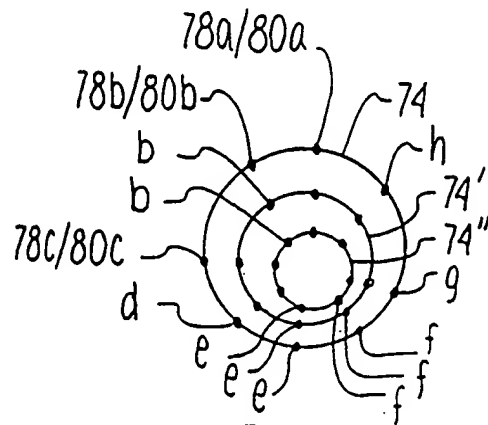


Fig. 6

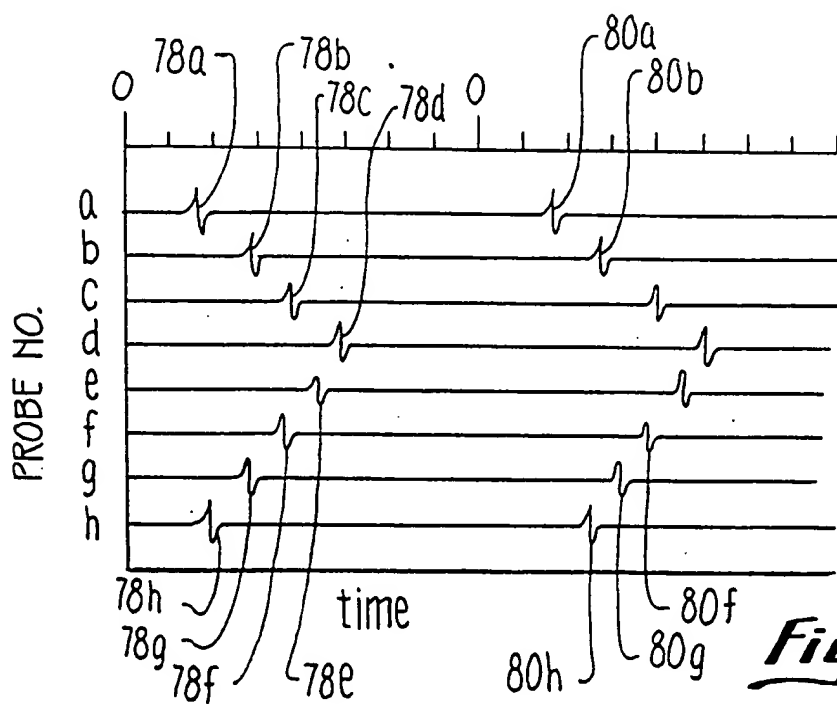


Fig. 5

INTERNATIONAL SEARCH REPORT

national application No.

PCT/US93/07881

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) : A61B 5/042

US CL : 128/642

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/642; 607/122,123

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A, 4,289,138 (Halvorsen) 15 September 1981, see entire document.	1-17
A	US,A, 4,522,212 (Gelinis) 11 June 1985, see entire document.	1-17
A	US,A, 4,602,642 (Barrington) 29 July 1986, see entire document.	1-17
A	US,A, 4,699,147 (Chilson) 13 October 1987, See entire document.	1-17
A	US,A, 4,862,887 (Weber) 05 September 1989, see entire document.	1-17



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	*T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*A document defining the general state of the art which is not considered to be part of particular relevance	*X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
*E earlier document published on or after the international filing date	*Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
*L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z document member of the same patent family
*O document referring to an oral disclosure, use, exhibition or other means	
*P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

10 November 1993

Date of mailing of the international search report

11 JAN 1994

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. NOT APPLICABLE

Authorized officer

LEE COHEN

Telephone No. (703) 308-2998

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☒ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☒ **FADED TEXT OR DRAWING**
- ☒ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☒ **SKEWED/SLANTED IMAGES**
- ☒ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.